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In re Application of :  
MILLER et al :  
Serial No.: 08/487,312 : Decision on Petition  
Filing Date: 7 JUNE 1995 :  
Attorney Docket No. 220002016004 :

This letter is in response to the Petition filed on 19 May 2003 to reopen prosecution under 37 CFR 1.198. The delay in acting upon this petition is regretted.

## BACKGROUND

A review of the file history shows that this utility application was filed on 7 June 1995 under 35 USC 111(a). This application is a continuation of 07/480,745, filed 15 February 1990, now allowed, which is a continuation of 07/090,937 filed 28 August 1987, now abandoned, which is a continuation of 06/489,557, filed 28 April 1983, now abandoned, and which is a continuation of 06/181,348, filed 26 August 1980, now abandoned.

The Office action mailed out a restriction requirement on 24 November 1995, which divided the claim set into two inventions, DNA and protein.

Applicants elected Group II, claim 19 drawn to protein, without traverse on 28 February 1996. Claim 19 is drawn to bovine Growth Hormone (bGH) made by culturing host cells which comprise recombinant DNA encoding bGH and recovering the bGH from the culture.

On 13 May 1996, the Office mailed an action objecting to claim 19 for depending upon a non-elected claim and rejecting claim 19 under 35 USC 102 or 103, as being anticipated by, or in the alternative, as obvious over Daniels et al (US Patent No. 3,265,579). The examiner reasoned that Daniels' growth hormone appeared to be substantially similar to that claimed and that the burden of proof was on Applicants to demonstrate a novel or unobvious difference between the claimed product and that of the prior art.

Applicants responded in August 1996 with arguments, an amendment to claim 19 and an amendment adding new claims 20-22 which depend upon claim 19. Applicants argued that the claimed bGH was materially different from the bGH described by Daniels in the ultimate safety of the product. Applicants argued that Daniels' bGH may contain the causative agent of Bovine Spongiform Encephalitis (BSE) while the recombinantly produced bGH claimed would not. Applicants provided several references in support of these arguments in an Information Disclosure Statement.

The Office mailed a Final Office action on 16 October 1996, maintaining the rejection under 35 USC 102 or 103. The Examiner reasoned that the claims are product-by-process claims and burden was placed upon applicants to prove by comparative evidence a patentable difference between the claimed product and that described by Daniels.

Applicants filed a Notice of Appeal on 17 January 1997, concurrent with a request for reconsideration. Applicants argued that the two products differ in degree of purity and differ in that Daniels has a significant risk factor when used in cattle while the claimed one does not. Applicants argued that the risks attached to the use of a product are as much a property of a product as any physical characteristics thereof.

An Advisory action was mailed on 14 February 1997, stating that:

the request for reconsideration has been considered but does not overcome the rejection because no evidence of record has been presented to show that the bGH preparation of Daniels et al contained anything other than bGH. Applicants' bGH does not distinguish over the prior art.

Applicants filed an Appeal Brief on 18 June 1997. The Appeal Brief argued that the claimed bGH prepared by recombinant method has the inherent property conferred by the process by which it is made, of a warranty of freedom from the causative agent of BSE.

The Examiner's Answer was mailed on 3 September 1997, which considered the Appeal Brief and maintained that Applicants have not sufficiently distinguished the claimed bGH from that of the prior art.

A reply brief was filed on 15 October 1997, further arguing product by process limitations.

Various letters were sent from the Office on 10 November 1997, 8 December 1997, 25 March 1998, 19 July 2002. Applicants also submitted various papers on 17 Nov 1997, 9 March 1998, and 31 May 2002. None of these were directed at the substance of the outstanding rejections.

The Hearing Notice was sent from the Office on 23 October 2002. The Hearing was confirmed on 25 November 2002. On March 26 2003, the Board of Patent Appeals and Interferences affirmed the Examiner.

This petition was timely filed on 19 May 2003, within two months of the Board's decision.

## DISCUSSION

The file record and the petition have been considered carefully.

The petition asks that prosecution be reopened to permit Applicants to submit the evidence enclosed with this petition. The petition asserts that considerable evidence of commercial success of the claimed subject matter has accumulated between the time prosecution was closed in this case and the present. The petition contains several exhibits (B-G) dated from 3 February 1997 (Exhibit B) to the year 2000 (Exhibit G), which describe sales figures of Applicants' bGH protein, which has been marketed by Monsanto under the trademark Posilac ®.

A review of the prosecution history shows that commercial success had not been submitted in arguments or evidence by Applicants in response to the rejection under 35 USC 103(a). Because commercial success is one of the secondary considerations relevant to resolving the issue of nonobviousness and because the evidence was obtained after prosecution was closed, the petition provides sufficient cause for applicants to present the evidence of commercial success before the Examiner.

Petitioner provides two reasons for reopening prosecution. The first reason, request to submit evidence of commercial success, given is sufficient basis to grant the petition. Since Petitioner's first reason is good cause for granting the petition, it is unnecessary to consider the second argument.

## DECISION

The petition is **GRANTED** for the reasons set forth above. Finality of the Office action mailed 16 October 1996 has been withdrawn. Prosecution is reopened.

Applicants are given **TWO MONTHS** in which to submit evidence enclosed in the petition to the examiner for consideration.

Should there be any questions with regard to this letter, please contact Special Program Examiner Julie Burke by letter addressed to the Director, Technology Center 1600, P.O. Box 1450, Alexandria VA 22313-1450 or by telephone at (571) 272-0512.

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